

Notice of Allowability

Application No.

08/637,752

Examiner

Mary E. Mosher, Ph.D.

Applicant(s)

KERN ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/28/2004.
2. ☒ The allowed claim(s) is/are 12,13 and 17-21.
3. ☒ The drawings filed on 02 May 1996 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

On reconsideration, the rejection based on Shenk et al 6489162 is withdrawn. Applicant has amended the claims to state that the monoclonal antibody is capable of detecting AAV2 capsid or capsid protein in an ELIZA assay, immunofluorescence, or Western blotting. The examiner cannot determine whether or not the antibody of Shenk inherently possessed the recited characteristics. While it does seem probable that an antibody which immunoprecipitates a capsid protein would recognize the protein in one of the assays, the examiner has been unable to provide any additional evidence regarding the characteristics of the specific antibody disclosed by Shenk. While it is common in this situation to cite *In re Best 195 USPQ 430 (CCPA 1977)* and shift the burden to the applicant to distinguish the old product from the claimed product, this approach presupposes that the old product is enabled. The disclosure of a monoclonal antibody in Shenk does not permit one skilled in the art to reproduce that specific monoclonal antibody. Therefore Shenk does not meet the standard required for anticipation. In regard to obviousness, secondary considerations must be considered. It might have been routine to make a monoclonal antibody similar to Shenk's, however the prior art provides no strong motivation to do so. In contrast, applicant has disclosed an unexpected association between AAV2 infection and spontaneous abortion and provided a new and unexpected diagnostic utility for anti-AAV2 monoclonal antibodies. When the new and unexpected use is weighed against the weak motivation in the prior

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art, the balance tips in applicant's favor. Therefore both alternative rejections under 102(e) and 103 are withdrawn.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800-1600

2/4/05